

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2001 list were published in the Federal Register in June 2001.

Supplemental Approvals

NADA Number: 140-338

This supplemental application provides for subcutaneous route of administration of ceftiofur sodium powder in cattle.

Trade Name: Naxcel® Sterile Powder
Ingredients: Ceftiofur sodium
Sponsor: Pharmacia & Upjohn Co.
Approval Date: May 29, 2001
Status: Prescription only
Route: Subcutaneous
Species: Cattle
Drug Form: Powder for reconstitution
Concentration: 50 milligrams per milliliter of reconstituted solution
Indications: For the treatment of Bovine Respiratory Disease (BRD) associated with *Pasteurella multocida*, *Pasteurella haemolytica*, and *Haemophilus somnus* and for the treatment of acute bovine interdigital necrobacillosis (foot rot) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.
Tolerance: 21CFR 556.113 Ceftiofur: Tolerances are established for residues of desfuroylceftiofur (marker residue) in edible tissues at 8 parts per million (ppm) in kidney (target tissue), 2 ppm in the liver, 1 ppm in muscle, and 100 parts per billion in milk. The Acceptable Daily Intake (ADI) for total residues of ceftiofur is 30 micrograms per kilogram of body weight per day.
Withdrawal: Zero days
Patent Number: 4,464,367
Exclusivity: 3 years

Expiration Date: August 7, 2001

21CFR 522.313

Change of Sponsor

NADA Number: 008-804

From: Pfizer, Inc.
To: Phibro Animal Health, Inc.
One Parker Plaza
Fort Lee, NJ 07024
Drug labeler code: 066104

NADA Number: 038-439

From: Pfizer, Inc.
To: Phibro Animal Health, Inc.
One Parker Plaza
Fort Lee, NJ 07024
Drug labeler code: 066104

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 095-143

From: Pfizer, Inc.
To: Phibro Animal Health, Inc.
 One Parker Plaza
 Fort Lee, NJ 07024
 Drug labeler code: 066104